



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-21-0199]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Import Permit Applications (42 CFR 71.54) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on October 21, 2020 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Import Permit Applications (42 CFR 71.54) (OMB Control No. 0920-0199, Exp. 04/30/2021) - Revision - Center for Preparedness and

Response (CPR), Centers for Disease Control and Prevention (CDC) .

Background and Brief Description

Section 361 of the Public Health Service Act (42 U.S.C. 264), as amended, authorizes the Secretary of Health and Human Services to make and enforce such regulations as are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. Part 71 of Title 42, Code of Federal Regulations (Foreign Quarantine) sets forth provisions to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the United States. Subpart F - Importations - contains provisions for the importation of infectious biological agents, infectious substances, and vectors (42 CFR 71.54); requiring persons that import these materials to obtain a permit issued by the CDC.

The Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States form is used by laboratory facilities, such as those operated by government agencies, universities, and research institutions to request a permit for the importation of biological agents, infectious substances, or vectors of human disease. This form currently requests applicant and sender contact information; description of material for importation;

facility isolation and containment information; and personnel qualifications. CDC plans to revise this application to:

- (1) Remove question 10 "Will the permittee be the courier of the imported biological agent?" from Section A since it is the same question found in Section C, Question 1.
- (2) Add example to Section F, Question 2 for clarity to read, "Protective Clothing (e.g., laboratory coat)."

These revisions will not affect the burden hours.

CDC received one comment regarding this notice. The commenter requested that the contact information for the biosafety officer field be mandatory. The commenter also requested that communications regarding the permit application be sent to the biosafety officer and permittee. CDC made no changes based on these comments as these recommendations did not request changes to the form but requested changes on how the program processes the application.

The Application for Permit to Import or Transport Live Bats form is used by laboratory facilities such as those operated by government agencies, universities, research institutions, and for educational, exhibition, or scientific purposes to request a permit for the importation, and any subsequent distribution after importation, of live bats. This form currently requests the applicant and sender contact information; a description and intended use of bats to be imported; and facility isolation and containment information. CDC does not plan to revise this application.

The Application for Permit to Import Infectious Human Remains into the United States is used by facilities that will bury/cremate the imported cadaver and educational facilities to request a permit for the importation and subsequent transfers throughout the U.S. of human remains or body parts that contains biological agents, infectious substances, or vectors of human disease. This form will request applicant and sender contact information; facility processing human remains; cause of death; biosafety and containment information; and final destination(s) of imported infectious human remains. CDC does not plan to revise this application.

Due to the implementation of eIPP and the applicants ability to complete the applications on-line without the need of the guidance document, the "Guidance Document for Completing Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States" is no longer needed. As such, the total burden hours of 333 for applicants to review this document was reduced and this entry was removed from the burden table.

The Application Requesting to Import Live Bats is used by laboratory facilities such as those operated by government agencies, universities, research institutions, and for educational, exhibition, or scientific purposes to request a permit for the importation of bats. Based on information from eIPP, IPP receives three "Application Requesting to Import Live Bats" requests per year. It takes applicants 20 minutes to

complete the application. The number of applicants was reduced from ten to three to accurately reflect the requests received. As such this change, the total burden hours from three to one.

Due to the implementation of eIPP and the applicants' ability to complete the applications on-line without the need of the guidance document, the "Guidance Document for Completing Application Requesting to Import Live Bats" is no longer needed. As such, the total of two burden hours for applicants to review this document was reduced and this entry was removed from the burden table.

Annualized burden hours were calculated based on data obtained from CDC import permit database on the number of permits issued on annual basis since 2015, which is 2,000 respondents. Due to the implementation of eIPP in 2020 which increased response efficiency and the applicants' ability to complete the applications on-line without the need of the guidance documents, the burden hours were reduced. Total response burden decreased from 1355 hours to 764 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors	Application for Permit to Import Biological Agents, Infectious Substances and Vectors of	2000	1	20/60

	Human Disease into the United States (42 CFR 71.54)			
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors	Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States (42 CFR 71.54) - Subsequent Transfers	380	1	10/60
Applicants Requesting to Import Live Bats	Application for a Permit to Import Live Bats (42 CFR 71.54)	3	1	20/60
Applicants Requesting to Import Infectious Human Remains into the United States	Application for Permit to Import Infectious Human Remains into the United States (42 CFR 71.54)	100	1	20/60

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